IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
OXFORD DIVISION

UNITED STATES OF AMERICA
ex rel. KEVIN GRAY — PLAINTIFF

v. — CIVIL ACTION NO: 3:15-CV-127-MPM-JMV

MITIAS ORTHOPAEDICS, PLLC,
AND HANNA M. MITIAS, M.D. — DEFENDANTS

MEMORANDUM IN SUPPORT OF THE DEFENDANTS' JOINT MOTION TO DISMISS THE COMPLAINT

I. Introduction

This is an action to recover damages and penalties brought pursuant to the False Claims Act ("the Act"). The plaintiff alleges that the defendants treated patients with hyaluronic acid ("HA"), a viscosupplementation agent used to treat osteoarthritis of the knee, that was not FDA approved, and that as a result, the HA was *per se* not reimbursable by various government health care benefit programs (collectively "Medicare"). The complaint also alleges that the defendants falsely represented to Medicare that they were using name brand variants of HA as opposed to compounded or generic HA, also causing the HA to be *per se* not reimbursable by Medicare.

In the Supreme Court's landmark *Escobar* decision from 2016, the Court clarified that the materiality element of a claim under the Act is a "rigorous" and "demanding" standard, such that a party's noncompliance with contractual or regulatory provisions must go "to the very essence of the bargain" or be "so central to" a transaction to be actionable under the Act. The Court also incorporated the scienter requirement, that a violation of the Act be committed knowingly, into the materiality calculus. It is not enough for a plaintiff to plead that a false claim was material to the government's decision to pay. A plaintiff must also plead with the requisite

plausibility that the defendant knew the requirement he was violating was material to the government's decision to pay.

The only allegation in the complaint regarding materiality consists of the bare naked declaration that Medicare would not have paid the claims had it known the HA used by the defendants was not a name brand, FDA approved version. That allegation, without some substantive factual support, does not establish materiality. Just because the government could have refused to pay a claim had it known of a defendant's noncompliance with certain provisions found in sub-regulatory guidance, does not make the particular act of noncompliance material for purposes of the Act. Conversely, under *Escobar*, Plaintiff's allegation that the defendants believed they could utilize the relevant billing codes because the description in the codes included "derivatives" of HA, and because defendants believed a letter they had received authorized the use of the codes is strongly indicative of *im*materiality. Therefore, Plaintiff has not stated a claim for which relief can be granted under the Act or for payment by mistake/unjust enrichment at common law (which require materiality, too).

For the reasons stated below, defendants' motion to dismiss should be granted.

II. The Allegations in the Complaint

The ultimate allegation in the complaint, that the claims for payment submitted by the defendants for compounded HA were false, are based on two distinct premises. First, the complaint alleges that the defendants treated patients with HA that was not an FDA approved medical device, and, second, that the defendants submitted claims for payment that falsely represented the device used was a name brand version of HA. [Dkt. 37 ¶ 75.]

In advancing these two alternate premises, the complaint does not identify any statutory or regulatory authority to support its claim of materiality. The single statute cited in the

complaint, 21 U.S.C. § 360c, describes the process used for a medical device manufacturer to seek classification of a medical device as a class I, II or III device. The plaintiff's assertion that this statute identifies "intra-articular hyaluronic acid products [as a] Class III medical device[] under the [Food, Drug & Cosmetic Act] requiring FDA approval," is not true. [Dkt. 37 ¶ 26.] Section 360c does not identify any specific product as a medical device.

The complaint does not plead any factual allegations to support its "naked" assertion that Medicare only pays for the use of viscosupplements that have been pre-approved by the FDA as Class III medical devices. This conclusory allegation is the only attempt by the plaintiff to satisfy its obligation to explain "how" the claims at issue were false. The second premise is advanced in much the same way. That is, by making the conclusory allegation that only name brand HA was "reimbursable" by Medicare. Again, no factual allegations are pled to establish the required plausibility of this conclusory allegation.

The basic purpose of the complaint is to inform the court and the defendants of the legal duty that was allegedly violated. The complaint in this matter does so as if the duty it alleges the defendants violated is a common law duty. It was not. Without identifying the source that gives rise to the legal duty the defendants are alleged to have violated, the complaint fails to establish all of the elements required by Rule 9(b) and *Escobar*.

III. Standard for Motion

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged."

Id. "A complaint is insufficient if it offers only labels and conclusions, or a formulaic recitation of the elements of a cause of action." *Id.* (quotation marks omitted). Even before it decided *Iqbal* and *Twombly,* the Supreme Court had long since held that courts were "not bound to accept as true a legal conclusion couched as a factual allegation." *Papasan v. Allain,* 478 U.S. 265, 286 (1986).

With respect to circumstances that allegedly constitute fraud under the Act and at common law, a plaintiff must satisfy not only the plausibility standard of Rule 8, but also the stricter particularity pleading standard of Rule 9(b), which "requires, at a minimum, that a plaintiff set forth the 'who, what, when, where, and how' of the alleged fraud." *U.S. ex rel. Shupe v. Cisco Sys., Inc.*, 759 F.3d 379, 382 (5th Cir. 2014). The materiality element is subject to Rule 9(b). *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 2004 n.6 (2016) (hereinafter "*Escobar*").

IV. Applicable Law

"False Claims Act plaintiffs must … plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of materiality." *Escobar*, 136 S. Ct. at 2004 n.6. Rule 8 "demands more than an unadorned, the-defendant-unlawfully-harmed-me-accusation." *Iqbal,* 556 U.S. at 678. "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Id.*, (quoting *Twombly,* 550 U.S. at 555). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Id.*, (quoting *Twombly,* 550 U.S. at 557). In addition to the allegation that a defendant is legally liable for the identified misconduct, a complaint must also include "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*, (quoting

Twombly, 550 U.S. at 556). The complaint must include facts that are more than "'merely consistent with' a defendant's liability" if the pleader is to cross "the line between possibility and plausibility of 'entitlement to relief.'" *Id.*, (quoting *Twombly*, 550 U.S. at 557).

When considering the sufficiency of a complaint, a court is generally required to accept as true the well-pleaded factual allegations in a complaint. This notion, however, does not apply to legal conclusions included in a complaint. *Id.* at 678. The court is not obliged to accept as true "legal conclusions couched as factual allegations." *Id.* This was true well before the Court decided *Iqbal* and *Twombly*. *See Allain*, 478 U.S. at 286. "While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Iqbal*, 556 U.S. at 679. When facing a motion to dismiss, "a court can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." *Id.* On the other hand, if a complaint includes "well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id.*

Before the Supreme Court's watershed decision in *Escobar*, most courts analyzed materiality in cases brought under the Act by considering "whether the false statement [had] a natural tendency to influence agency action or [was] capable of influencing agency action." *U.S. ex rel. Berge v. Trs. of Univ. of Ala*, 104 F.3d 1453, 1459 (4th Cir. 1997). After *Escobar*, courts have dutifully begun to apply what the Supreme Court called a "rigorous" and "demanding" materiality standard for cases brought under the Act. 136 S. Ct. at 1996, 2002, 2003, 2004 n.6. The Court's significant enhancement of the burden of proving materiality was based on its "concerns about fair notice and open-ended liability" because "billing parties are often subject to thousands of complex statutory and regulatory provisions." *Id.* at 2002-3. According to the

Supreme Court, the Act is neither "an all-purpose antifraud statute" nor "a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Id.* In addition to being subject to the general pleading requirements of Rule 8, the materiality element is also subject to Rule 9(b). *Escobar*, 136 S. Ct. at 2004 n.6.

To prove a knowing violation of the Act, the plaintiff must prove that the defendants either had "actual knowledge of the information;" or "act[ed] in deliberate ignorance of the truth or falsity of the information;" or "act[ed] in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3129(b). To that end, negligence is an absolute defense to liability under the False Claims Act. The "*mens rea* requirement is not met by mere negligence or even gross negligence." *U.S. ex rel. Farmer v. City of Houston,* 523 F.3d 333, 339 (5th Cir. 2008). The Court in *Escobar* not only enhanced the burden a plaintiff must meet to prove materiality, the Court also brought the scienter requirement into the materiality analysis. *Escobar,* 136 S. Ct. at 1996 (emphasis added). It is not enough for a plaintiff to plead that a false claim was material to the government's decision to pay. A plaintiff must also plead with the requisite plausibility that the defendant knew its falsehood was material to the government's payment decision ***at the time it submitted its claim***. *Id.* "What matters is not the label that the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Id.* Federal district courts have enforced this requirement post *Escobar*. *See U.S. ex. rel. Durkin v. Cty. of San Diego*, 2018 WL 3361148, at *5 (S.D. Cal. July 10, 2018) ("The Supreme Court construed the scienter requirement together with the materiality requirement to mean that a claimant must not only know about a violation of a particular statutory or regulatory provision, but that the claimant must also know that compliance with that provision is material to the government's payment

decision."); *U.S. v. Salus Rehab. LLC*, 304 F. Supp. 3d 1258, 1262 (M.D. Fla. 2018) ("In other words, the False Claims Act requires the relator to prove both that the non-compliance was material to the government's payment decision and that the defendant knew at the moment the defendant sought payment that the non-compliance was material to the government's payment decision.").

CMS[1] supplements the Social Security Act with federal regulations and with sub-regulatory guidance and policy documents, such as the Medicare Benefits Policy Manual and Local Coverage Determinations ("LCDs") created by regional contractors. An action brought pursuant to the Act cannot be based on a policy or sub-regulatory guidance documents that did not comply with the notice-and-comment rulemaking procedure found in 42 U.S.C. § 1395hh(a)(2). Before the government can establish "a substantive legal standard governing the …payment for services…under [Medicare]" the law requires "the government to provide public notice and a 60-day comment period." *Azar v. Allina Health Services*, 139 S.Ct. 1804, 1809 (2019), (citing 42 U.S.C. § 1395hh(a)(2)). A policy that affects a provider's right to payment is substantive. *Id.* at 1811. The manner in which Medicare labels a policy or guidance document has no effect on whether it establishes a substantive legal standard. *Id.* at 1812. "[C]ourts have long looked to the *contents* of the agency's action, not the agency's self-serving *label*, when deciding whether statutory notice-and-comment demands apply. *Id.*(emphasis in original), (citing *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (CADC 1984) (en banc)); *Guardian Fed. Sav. & Loan Assn. v. Federal Sav. & Loan Ins. Corp.*, 589 F.2d 658, 666-667 (CADC 1978).

[1] CMS is the Centers for Medicare and Medicaid Services. CMS manages the Medicare program and it is a component of the United States Department of Health and Human Services.

V. Argument

The foundational legal allegations made in the complaint in this case lack factual allegations to support them and as such, they do not meet the *Escobar* materiality standard. According to the complaint

> … each and every claim submitted to the Federal Health Program for reimbursement for using a viscosupplementaiton agent was a false claim, both because the misbranded/adulterated product was not covered by the Federal Health Programs and because Mitias falsely billed under the code for FDA-approved product that was not administered. These false claims were material to reimbursement – had the Federal Health Benefit Programs been aware that Mitias had used the non-FDA approved viscosupplementation devices, they would not have paid Mitias for the claims.

(emphasis added) [Dkt. 37 ¶ 75.] The plaintiff's allegation is simple. The claims were all false because the plaintiff presently says Medicare would not have paid them had it known that the HA used was not one of the FDA approved name brand variants. These allegations fail to sufficiently plead a material false claim because they fail to identify a properly enacted substantive legal standard that the defendants violated, i.e. something that told the defendants Medicare would not knowingly pay for the use of compound or generic HA at the time the claims were submitted. The complaint also fails to allege sufficient factual support to meet its pleading burden of showing that it is plausible that the defendants acted knowingly as opposed to negligently.

A. The Factual Allegations Made by Relator Do Not Establish a "Knowing" Violation

Paragraphs 41 through 73 include the factual allegations made by Relator in his original complaint. Many of these allegations establish that the defendants held an honest belief that the use of the compounded or generic HA was reimbursable generally, and specifically through the use of the Health Care Common Procedure Coding System ("HCPCS") codes that were used.

For example, the relator states that it was the defendants that reached out to him to inquire about purchasing and using Euflexxa, as opposed to Relator discovering the defendants through his own marketing activities. [Dkt. 37 ¶ 44.] Relator claims that the defendants freely disclosed to him, a total stranger, their allegedly illegal scheme to defraud the government the first time they ever met him. According to Relator, the defendants told him that they were using HA they obtained from U.S. Compounding, and not a "name brand." [Dkt. 37 ¶ 46.] The defendants told Relator that they were soliciting information from all the name brand manufacturers of HA "because they were no longer able to use" the compounded or generic HA. [Dkt. 37 ¶ 46.] The defendants told Relator that "changing regulations" were preventing them from obtaining and using the compounded or generic HA any longer. [Dkt. 37 ¶¶ 55, 59.] According to Relator, Dr. Mitias told him that the HA they were using could be billed under the name brand HCPCS codes because the descriptions of the codes included "derivatives" of HA. [Dkt. 37 ¶ 67.] Dr. Mitias also showed Relator a copy of a letter that he believed addressed the use of the HCPCS codes with the compounded or generic HA. [Dkt. 37 ¶ 68].

Virtually all of Relator's factual allegations undercut the allegation that the defendants were knowingly submitting false claims. According to Relator, the defendants openly discussed their use of compounded or generic HA, where they obtained the HA, the manner in which they billed for its use, why they believed they could no longer use the HA from U.S. Compounding, and why they believed they had been properly submitting claims for its use. None of these allegations plead factual support for the notion that the defendants knew that the use of an HA product that was not "name brand" was in any way material to Medicare's decision to pay. To the contrary, these factual assertions support the idea that the defendants were not aware of the

possibility that Medicare based its payment decision on whether they were using a particular "name brand" variant of HA.

The plaintiff has failed to plead a set of factual allegations that are sufficient to cross "the line between possibility and plausibility of 'entitlement to relief.'" *Iqbal.*, (quoting *Twombly,* 550 U.S. at 557.) Even if the court were to find that the facts pled are "consistent with the defendant's liability," that quantum of proof at the pleading stage is not sufficient. *Id.*

B. Allegation No. 1 – The claims were false because the HA was not FDA approved.

According to the complaint, the HA used by the defendants was "never subject to a PMA and never received FDA approval." [Dkt. 37 ¶ 39.] The ultimate conclusion is the HA was *per se* not reimbursable by Medicare because the HA was not an FDA approved device. [Dkt. 37 ¶ 75.] The complaint fails to attribute this legal conclusion to any statutory or regulatory authority. This is because no such *per se* prohibition exists regarding the reimbursement of devices that are not FDA approved.

According to the Code of Federal Regulations, "CMS uses the FDA categorization of a device as a *factor* in making Medicare coverage decisions." 42 C.F.R. § 405.201(a)(1) (emphasis added). In fact, that regulation includes examples of circumstances where non-FDA approved devices can be reimbursed by Medicare. *Id.* The plain and unambiguous language in the regulation establishes that CMS has discretion on whether to cover the use of a medical device, and that the FDA categorization of that device is only a "factor" CMS uses in making its coverage determination. *Id.* There is no statute, regulation or properly enacted sub-regulatory guidance that the plaintiff can rely upon to support the asserted legal conclusion that the claims for payment for non-FDA approved HA were *per se* not reimbursable by Medicare.

Presumably in support of its efforts to establish materiality, the plaintiff goes to great lengths to educate the court on the process ***a drug manufacturer*** must follow to have a medical device, particularly a class III medical device, approved for marketing by the FDA. In doing so, the complaint cites the court to one federal statute, 21 U.S.C. § 360c. [Dkt. 37 ¶ 26, n.1.] Contrary to what the complaint says, this statute does not classify "viscosupplements," or any other product for that matter, as a medical device, much less a device of a particular classification. 21 U.S.C. § 360c. It simply discusses the FDA's device classification authority and process. *Id.* The complaint also cites to Section 360c for the proposition that the "FDA requires a Premarket Application ("PMA") prior to approving a Class III device." [Dkt. 37 ¶ 38.] Obtaining approval to market a Class III medical device is the responsibility of ***the manufacturer*** of the device. The defendants are a doctor and his clinic. The complaint does not allege that the defendants illegally manufactured or marketed the HA. This statute does not establish that the claims for payment were material, or that HA would be subject to its provisions.

The plaintiff also discusses the manner in which it contends that "payments for most drugs and biologicals, including certain Class III medical devices administered in the physician's office are typically based on average sales price ("ASP") data." [Dkt. 37 ¶ 25.] The complaint alleges that the ASP data comes to the government from the ***manufacturer*** of the drug or device. [Dkt. 37 ¶ 25 (emphasis added).] The complaint does not allege that an end-user of a drug or device, i.e., a healthcare provider like the defendants, plays any role in establishing the ASP of a product. The same is true for the representation in the complaint about the percentage of payments made for single or bi-lateral injections. [Dkt. 37 ¶ 28.] This factual allegation is not cited or attributed to any particular authority. More importantly, the inclusion of these

conclusory allegations does nothing to establish that the claims submitted for payment by the defendants were materially false. How payment is calculated has nothing to do with whether the use of compounded or generic HA was material to Medicare's decision to pay or whether the defendants knew at the time they submitted the claims that it was material to that decision.

The complaint also fails to allege any factual allegations that, if true, would justify the court finding that the defendants knew that compounded or generic HA could have been a device as opposed to a drug in the first place. Perhaps the best example of this point can be seen in the manual where the relevant billing codes are found. The HCPCS codes referred to by the plaintiff in the complaint characterize HA as a "drug" as opposed to a device. *See* HCPCS Level II Standard Edition (Saunders), 2011-2015 eds. For example, the 2011 HCPCS manual lists the codes in the section entitled "Drugs other than Chemotherapy." 2011 HCPCS Level II Standard Edition (Saunders), 2011 at 209. The rest of the HCPCS manuals from the relevant time period consistently characterize HA as a "drug." It is also worth noting that the plaintiff has been investigating this matter for almost five years. Had it discovered any evidence from U.S. Compounding that established the defendants were made aware that the compounded or generic HA had not obtained the correct FDA approval for use, it certainly would have pled those facts to support its allegations. No such factual claims are included in the complaint.

The information about price calculation and the FDA device classification process do not establish that the use of compounded or generic HA was material to Medicare's decision to pay. The plain language of 42 C.F.R. § 405.201(a)(1) tends to establish that Medicare can, and in fact does at times, pay for the use of medical devices that are not FDA approved. The plaintiff has failed to sufficiently plead a material false claim under this theory of its case.

C. Allegation No. 2 – Medicare Would Only Pay for Name Brand HA Variants

The complaint alleges that the claims were false because the defendants used various HCPCS codes that were purportedly intended only for use with "name brand" variants of HA. [Dkt. 37 ¶¶ 74, 75.] While it is not entirely clear, the complaint appears to allege that Medicare assumed that any claims using the HCPCS codes identified in paragraphs 30 through 36 of the complaint were for the administration of the name brand product that was identified in the latter portion of the code. The complaint does not support this "naked" conclusory allegation with any factual support. The complaint attempts to buttress this argument by alleging that "[t]here is no HCPCS code for any 'generic' or 'compounded' intra-articular hyaluronic acid products, or intra-articular hyaluronic acid products that are not approved by the FDA." [Dkt. 37 ¶ 37.] This factual assertion is wrong.

All but one of the HCPCS codes at issue are described as follows by each version of the HCPCS manual in effect from 2011 through 2015: "Hyaluronan *or derivative*, [specific name brand listed for each different code], for intra-articular injection, per dose." Codes J7321, J7323, J7324 HCPCS Level II Standard Edition (Saunders), 2011 ed. (emphasis added). The remaining code, J7325, is described as "Hyaluronan *or derivative*, Synvisc or Synvisc-One, for intra-articular[.]" *Id.* (emphasis added). The following description is included in the HCPCS manual after the description of the first HA code, J7321: "Therapeutic goal is to restore visco-elasticity of synovial hyaluronan, thereby decreasing pain, improving mobility and restoring natural protective functions of hyaluronan in joint[.]" *Id.* The HCPCS codes specifically describe the billable product as either Hyaluronan or as a "derivative" of hyaluronan. *Id.* There are no instructions in the HCPCS manual that explain exactly what a "derivative" is or that the code is limited to the use of the specific name brand of the HA.

To accept the plaintiff's theory of liability as sufficiently pled, that the inclusion of the name brand product in the description of each code is sufficient to establish a plausibility that the defendants had the requisite knowledge that the use of non-name branded HA was material to Medicare's decision to pay, the court must assume that the defendants were somehow aware that the inclusion of the word "derivative" in the codes was apparently superfluous and meaningless. This is similar to the situation the court was faced with in *Durkin,* 2018 WL 3361148 at *5. In that case, the court held that Relator pled facts sufficient to support its claims that the alleged falsity was material to the decision to pay. *Id.* However, the court held that the relator had not pled facts sufficient to establish that the defendant himself had enough knowledge to satisfy the scienter requirement that the defendant know that the falsity was material to the decision to pay at the time he submitted the claim. *Id.* On its face, the complaint has failed to allege a single fact that, if true, would establish that the defendants knew that their use of compounded or generic HA with the relevant HCPCS codes would have caused Medicare to refuse payment.

The plaintiff alleges that the use of non-name brand HA was *per se* not reimbursable by Medicare. [Dkt. 37 ¶ 37.] This attempt to meet the "rigorous" and "demanding" materiality burden is thwarted by the same HCPCS manual the plaintiff relies on to support its allegations of fraud. HCPCS code J3490, defined as a code to be used for "unclassified drugs" specifically lists "hyaluronic acid" as one of the injectable drug substances that are reimbursable by using that code. *See* HCPCS Level II Standard Edition (Saunders), 2011 ed. through 2015 ed.

> "J3490 Unclassified drugs Bill on paper. Bill one unit. Identify drug and total dosage in "Remarks" field. Other: *...Hyaluronic Acid ..."*

Id. (emphasis added). (citation of other specific unclassified drugs included in the definition omitted). Code J3490, which has been in effect since January 1, 1997, does not list any of the

name brand HA variants that the plaintiff wrongly claims are the only variants of HA that are reimbursable by Medicare. *Id.* The inclusion of a non-specific HA as a reimbursable "unclassified drug" in every HCPCS manual during the relevant time frame inflicts a fatal blow on the plaintiff's factually unsupported and conclusory claim that Medicare would only pay for name brand, FDA-approved HA. Clearly, whether the HA used by a provider was an FDA approved "name brand" device or a compounded or generic version was not material to whether Medicare would reimburse a provider for its use.[2]

The terms of HCPCS code J3490 must be given the same weight that the plaintiff seeks to have attributed to the terms of the other HCPCS codes it cites to. It is clear from the description of code J3490 and the plain language of 42 C.F.R. § 405.201(a)(1) that neither FDA approval, or the manufacture of HA in a compounded or generic form is sufficiently material to Medicare's decision to pay to trigger liability under the Act. The plaintiff has failed to plead a material false claim under this theory as well.

D. Medical Necessity Allegations

While the complaint does not allege false claims based on a lack of medical necessity, it does contain a section entitled "Lack of Medical Necessity." The idea behind the plaintiff's assertions here are that the content of the cited medical records do not support the need for the viscosupplementaiton injections in the first place. There are no factual allegations made in the complaint that address this particular issue. The only citation to any standard by which the content of the patient records can be judged is to an LCD which portends to require additional documentation to justify the use of HA knee injections. The plaintiff cannot base an enforcement

[2] While it is certainly plausible that using code J3490 (as opposed to code J7321 Hyaluronan or *derivative*, Hyalgan or Supartz) ***could have*** had some effect on the manner in which reimbursement was made, the government's complaint fails to make any such allegation in that regard. Moreover, such an allegation would merely be a "garden-variety breach[] of contract" contemplated by Escobar, *not* a false claim.

action on the failure of a provider to comply with the terms of an LCD, because LCDs are not subject to the statutorily required notice and comment requirements in 42 U.S.C. § 1395hh(a)(2).

In order to form the basis for an enforcement action relating to the decision to pay, which is a substantive legal standard, a policy must be enacted consistent with the notice and comment rulemaking procedures required by the statute. *Azar v. Allina Health Services*, 139 S.Ct. 1804, 1809 (2019), (citing 42 U.S.C. § 1395hh(a)(2).) LCDs are not enacted through the use of the statutorily required notice and comment provisions of Section 1395hh(a)(2). To the extent the complaint is asserting that certain claims are false under the Act for failing to comply with the documentary standards established by an LCD, the plaintiff is foreclosed from doing so. Regardless, the allegations regarding medical necessity are bare bones, conclusory allegations that do not sufficiently plead facts to satisfy either the decision to pay or knowledge prongs of the materiality standard.

E. Allegations Regarding Harm, Provider Qualifications and Injection Practices

The complaint includes various conclusions and allegations that do not appear to relate to the substantive claims made in the complaint, but that are damaging to the defendants, and as such much be addressed. These allegations are untrue. Some of these false allegations are known to the plaintiff to be untrue.

The complaint makes several allegations regarding potential harm to patients. The general gist of these allegations is that the Premarket Application ("PMA") process is intended to ensure that Class III devices are safe to use. The complaint goes on to allege that Class III devices that do not have a PMA are "adulterated" and "misbranded." [Dkt. 37 ¶ 39.] Assuming, arguendo, that these claims are generally true, the plaintiff has no basis for including them in this complaint, because the FDA had since publicly declared that HA does not meet the statutory

definition of a medical device. "HA achieves its primary intended purpose of treatment of pain in [osteoarthritis] of the knee through chemical action within the body." 83 Fed. Reg. 64,844 (Dec. 18, 2018). "Under section 201(h) of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. § 321(h)) a device 'does not achieve its primary intended purposes through chemical action within or on the body.'" *Id.*

That being the case, the plaintiff is presently aware that HA, even during the time frame covered by the complaint, did not actually fall into the "adulterated," "misbranded" or other dangerousness characteristics that actual Class III devices have. In spite of now knowing the FDA had mischaracterized HA as a device for years, the plaintiff continues to allege that the defendants somehow placed patients at a risk of harm, by using a Class III device that had not been FDA approved.

The plaintiff's insistence on arguing that HA was a device and not a drug is understandable. If the HA was a drug (which we now know it was all along), then it was unquestionably reimbursable by Medicare. There is no statutory, regulatory or sub-regulatory requirement that drugs or biologicals provided to Medicare beneficiaries be FDA approved. There is also no statutory, regulatory or sub-regulatory requirement that compounded drugs be FDA approved in order to be considered reimbursable (i.e. "reasonable and necessary") by Medicare. CMS has, however, spoken directly to this point, telling the Government Accountability Office ("GAO") that Medicare pays for compounded drugs that comply with the FD&C Act. On September 23, 2014, in response to a GAO audit, CMS submitted a formal statement to the GAO regarding payment for compounded drugs.

> [Medicare] Part B policy for compounded drugs generally does not distinguish between compounded drugs that contain bulk drug substances or those prepared from FDA-approved drug products. Instead Medicare Part B policy recognizes the differences between

> compounded drugs and FDA approved manufactured drugs. **Payment for compounded drugs is permissible provided that the compounded drugs are prepared in a manner that does not violate the FDCA.**

GAO Report to Congress 15-85 at 32 (emphasis added). The complaint does not allege that the compounded HA used by the defendants was prepared in a manner that violated the FD&C Act, if in fact the HA was a drug as FDA now says it is.

Relator makes a number of allegations about the medical practice and billing procedures of the defendants that could not possibly have been known by Relator. For example, Relator alleges that "virtually the entire staff … were performing injections." [Dkt. 37 ¶ 51.] This allegation is not true, and the complaint does not specify what the source of Relator's knowledge is on this point. The same is true regarding the allegation that an ultrasound was used even if it was unnecessary. [Dkt. 37 ¶ 53.] Relator also alleges that a Radiology Technician performing the injections was "unqualified" to do so. [Dkt. 37 ¶ 52.] During the course of the last two years, the undersigned has addressed these allegations with the plaintiff, and has provided evidence that addresses these untrue claims.

Perhaps one of the most disturbing falsities contained in the complaint is the allegation by Relator that patients were harmed by "bad batch[es]" of HA obtained from U.S. Compounding. [Dkt. 37 ¶ 57.] This is a fabrication. Nothing of the sort has ever occurred during the time the defendants were using the compounded or generic HA. Even if it had occurred, that type of issue happens throughout the pharmaceutical industry. A cursory Google search reveals that some of the name brand HA variants cited in the complaint have been recalled over the years due to sterility issues in their manufacture. This allegation is specious and is false.

The plaintiff alleges that the defendants have directly misled patients about the source of the HA that was being used throughout the relevant time frame. [Dkt. 37 ¶ 58.] This is also a

blanket fabrication. Qualifying this allegation with the phrase "upon information and belief" does not relieve the plaintiff from its obligation to plead only those facts of which it believes it has evidence. Upon information and belief, over the course of the last five years, the plaintiff has not interviewed a single patient of the defendant. It stands to reason that if the plaintiff had actually interviewed patients and asked this question, it would have pled those facts in the complaint. No such allegations are included.

The allegations in paragraphs 61 and 62 are flatly untrue. These conversations never took place and this is not the manner in which the defendants billed Medicare. This is also an issue that the undersigned has discussed with the plaintiff during the last two years. The plaintiff has a sample of patient charts and the claims history that identifies the particular HCPCS codes billed for each patient encounter. The HCPCS code used by the defendants corresponded with the molecular weight associated with the dosage given. In other words, if a patient received a single shot injection of HA, the defendants billed for the corresponding HCPCS code that reflected a single shot injection of the same milligrams that was actually given to the patient. Had the plaintiff confirmed otherwise during its five year investigation, it would have pled those facts with specificity.

There are additional factual allegations by Relator that do not address either the decision to pay or knowledge prongs of the materiality issue. Many of these allegations are untrue, particularly those about the interaction between Relator and the defendants. None of these allegations suffice to plead a fact that in any way tends to establish the materiality of the two theories of fraud the plaintiff's complaint describes.

V. Conclusion

The plaintiff's complaint is based on unsupported allegations and conclusions, without pleading actual facts that, if true, would sufficiently plead those conclusions. The court should not assume the truth of legal conclusions, particularly those masked as facts. The court should certainly not presume as true legal conclusions that are directly contradicted by other evidence, such as properly enacted federal regulations like 42 C.F.R. § 405.201(a)(1) and HCPCS code J3490. Where actual facts are alleged in the complaint, principally by Relator, most of those facts actually support a finding of *im*materiality in that they tend to establish that the defendants were not aware of the purported materiality their actions would have had on Medicare's decision to pay.

If the plaintiff is aggrieved by the payments it made to the defendants, it has myriad ways to recoup those funds outside of bringing a False Claims Act lawsuit. This was the essence of the Court's holding in *Escobar*, that the Act is neither "an all-purpose antifraud statute" nor "a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Escobar*, 136 S. Ct. at 2002-3. While the plaintiff's pleading may well identify a possible improvident use of particular HCPCS codes by the defendants and violations of the FD&C Act ***by U.S. Compounding***, it has failed to identify a plausible, material false claim as it relates to the defendants. This court should grant the motion to dismiss, and the plaintiff should use another one of its available remedies to address the issues raised in the complaint.

Respectfully Submitted, this the 12th day of March, 2020.

/s/ J. Scott Gilbert
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CERTIFICATE OF SERVICE

I hereby certify that I have electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all counsel of record on this the 12th day of March 2020.

/s/ J. Scott Gilbert
J. Scott Gilbert